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Filed : April 30, 2002

### REMARKS

Claims 1, 2, 4, 5, and 10-12 have been cancelled. Claims 20-25 have been added. Claims 3, 6-9, and 15 have been amended. As a result of this amendment, Claims 3, 6-9, and 13-25 are presented for further prosecution. The changes made to the Specification and Claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

Support for the amendments to Claims 3, 6-9, and 13-25 can be found in the Specification and Claims as filed, for example:

(1) Support for amended Claim 3 can be found in paragraphs [0013], [0029], [0030], and [0036] in US 2002/0183856 A1.

(2) Support for amended Claim 6 can be found in paragraphs [0031] and [0037] in US 2002/0183856 A1.

(3) Support for amended Claim 7 can be found in paragraphs [0032] and [0037] in US 2002/0183856 A1.

(4) Support for amended Claim 8 can be found in Table 2 in US 2002/0183856 A1.

(5) support for amended Claim 9 can be found in paragraph [0030] in US 2002/0183856 A1.

(6) Support for new Claim 20 can be found in paragraphs [0030] and [0036] in US 2002/0183856 A1.

(7) Support for new Claim 21 can be found in paragraph [0035] in US 2002/0183856 A1.

(8) Support for new Claims 23-25 can be found in paragraphs [0067] to [0074] in US 2002/0183856 A1.

### **Rejection under 35 U.S.C. §112, second paragraph**

Claims 5-12 were rejected as being indefinite for the recitation of "the" in "the elastic modulus" in line 2 of claim 5 as lacking an antecedent basis. Claims 4 and 5 have been cancelled, rendering this rejection moot.

### **Claim Rejections Under Obviousness-Type Double Patenting**

Claims 1-16 were rejected under the doctrine of obviousness type double patenting as unpatentable over the Claims 1-17 of United States Patent No. 6,514,291 ('291). The Examiner

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believes that the claims are not patentably distinct because the copolymer forming an artificial dura mater of '291 encompasses the instant amorphous and low crystalline polymer as evidenced by the same elastic modulus as claimed in claim 8.

However, the presently amended claims provide an artificial dura mater which is characterized in that "the amorphous or low crystallinity polymer" with specific properties is integrally molded with "the structural reinforcement" with specific properties to form one united body. Such an artificial dura mater is not disclosed in any of the Claims 1 to 17 of '291.

The Examiner's position is that the copolymer of Claim 1 of US 6514291 has the same elastic modulus as the amorphous or low crystallinity polymer of Claim 8 of the invention. However, this is incorrect since the items being compared in the amended claims and '291 are explicitly different from each other as described below.

Even if the storage elastic modulus of '291 (Column 7, line 14 to 20) were the same as the elastic modulus of the present invention (US 2002/0183856 A1, paragraph [0056]) as stated by the Examiner, '291 refers to the storage elastic modulus of the artificial dura mater itself having a three-layer structure (Examples 1 to 3, and Table 3 of '291) while the presently claimed invention refers to the elastic modulus of the amorphous or low crystallinity polymer forming the artificial dura mater (Examples 1 to 4, and Table 2 of the specification of this application). Thus, Applicants submit that the Examiner's interpretation is incorrect.

In conclusion, the presently claimed invention is patentably distinct from '291 because it is integrally molded with "the structural reinforcement" with specific properties to form one united body. And further, the Examiner's interpretation of the elastic modulus is incorrect because in each case it refers to a different structure, and Applicants respectfully request withdrawal of the double patenting rejection.

**Rejection under 35 U.S.C. §102(b) and 103(a)**

Claims 1-16 were rejected under 35 U.S.C. §102(b) as anticipated by, or in the alternative, obvious over Taira et al (US 5,861,034) and Williams et al (US 6,548,569). Further, anticipation and obviousness rejections are as follows: The Examiner rejected Claims 1-16 under 35 U.S.C. §102(e) as anticipated by, or in the alternative, obvious over Yamauchi, et al (US 6,514,291). Claims 1, 2, and 5-9 are rejected under 35 U.S.C. §102(e) as anticipated by, or in the alternative, obvious over Williams, et al (US 6,548,569). Claims 1-18 are rejected under 35 U.S.C. §103(a) as obvious over Taira, et al (US 5,861,034) Yamauchi, et al (US 6,514,291) in

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view of Rosen et al. (US 4,364,126). Claims 1-16 and 19 are rejected under 35 U.S.C. §103(a) as obvious over Rosen et al. (US 4,364,126) in view of Taira, et al (US 5,861,034) or Yamauchi, et al (US 6,514,291). Claims 1-19 are rejected under 35 U.S.C. §103(a) as obvious over Williams, et al (US 6,548,569) in view of Taira, et al (US 5,861,034) or Yamauchi, et al (US 6,514,291) and Rosen et al. (US 4,364,126).

Yamauchi (US 6,514,291) discloses an artificial dura mater which is a three layer structure having two sheets of a biodegradable synthetic polymer with a reinforcement sandwiched therein, the three-layer structure having a specific storage elastic modulus.

Taira (US 5,861,034) teaches a three layer artificial dura mater made of two layers of a biodegradable copolymer of lactic acid and  $\epsilon$ -caprolactane and a biodegradable reinforcement integrated with the sheets made of the copolymer.

Williams (US 6,548,569) discloses medical devices comprising polyhydroxyalkanoate ("PHA") biopolymers, and discloses that the PHAs can be combined with additional non-PHA materials. Table 1 of Williams shows that the glass transition temperature (T<sub>g</sub>) of PGA is 35°C. Williams does not teach a layered structure.

Rosen (US 4,364,126) discloses that the preferred material or a protective band adopted to circumscribe a prosthetic heart valve is polypropylene, polyethylene, nylon, polyvinylchloride, etc. Rosen does not teach a layered structure.

As described above, the artificial dura mater of the present invention is characterized in that it is a two-layer structure with "the amorphous or low crystallinity polymer" with specific properties integrally molded with "the structural reinforcement", each layer having the recited specific properties to form one united body.

**With respect to novelty, the following applies:**

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ... There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

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Taira et al (US 5,861,034), Yamauchi et al (US 6,514,291), and Williams et al (US 6,548,569) do not teach each and every element of the claimed invention because they do not teach a two layered structure or that the polymer is integrally molded with “the structural reinforcement” with the specific properties recited (the amorphous low crystallinity polymer having a degree of crystallinity of 20% or lower and an elastic modulus at 5% extension of greater than 10 MPa or lower) to form one united body. Further, Yamauchi et al and Taira et al teach only a three layer artificial dura mater having a reinforcement sheets sandwiched between the two copolymer layers. Thus, none of the three references anticipates the claimed invention and Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102.

**With respect to obviousness**, the law is clear that three basic criteria must be met to establish a *prima facie* case of obviousness: (MPEP ¶2143):

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references, when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1440 (Fed. Cir. 1991)).

As stated in the response to the rejection under 35 U.S.C. §102 above, none of the recited references alone or in combination teaches all of the claimed elements because none of the references alone or in combination teaches a two-layer artificial dura mater formed by integrally molding “the amorphous or low crystallinity polymer” and “the structural reinforcement” with the specific properties as shown in Table A. Further, the combination of the two layers with differing specific properties is not disclosed in any of the references. The use of such a polymer and a reinforcement allows an artificial dura mater to prevent damage to the brain surface and to prevent cerebrospinal fluid leakage even when either a bioabsorbable polymer or a non-bioabsorbable polymer is used for the material of “the polymer” and “the structural reinforcement.”

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Table A

Claim	Parameter	Amorphous or Low Crystallinity Polymer	Structural Reinforcement
3	Elastic modulus at 5% extension	10 MPa or lower	Greater than 10 Mpa
6	Tg	15°C or lower	Higher than 15°C
7	Tensile elongation at break	200% or greater	Less than 200%

The above-cited references teach biodegradable polymers and reinforcements, however they neither teach nor suggest adopting the claimed polymer and a reinforcement as shown in Table A. Thus, the claims do not teach all of the claim elements and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Claims 20 to 25 are newly added. These claims are novel and are patentably distinct since these claims are not suggested by the cited references.

#### Conclusion

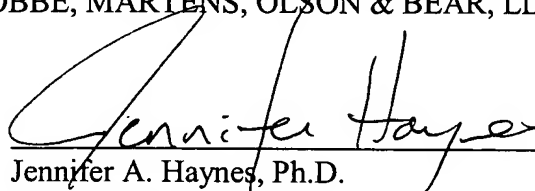
In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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